

## **Remarks**

### **Claims**

Claims 1, 3-5, and 9-19 are pending. Claims 1, 3-5, and 9-19 are amended. No new matter is added. The foregoing amendments and cancellations are made solely to advance prosecution, without acquiescence to any rejection or disclaimer of subject matter removed by amendment, and reserving all rights to pursue such subject matter in continuing or divisional applications claiming the same right of priority as the present application.

### **Response to §112, 2<sup>nd</sup> para. Rejection**

Examiner rejected claims 1, 3-5, and 9-19 under 35 USC § 112, 2<sup>nd</sup> para. for allegedly lacking antecedent basis. Claims 1, 3-5, and 9-19 are amended, therefore, applicant believes this rejection is overcome.

### **Response to §103(a) Rejection**

Examiner rejected claims 1, 3-5, 9-19 under 35 USC § 103(a) and argued that the claims were unpatentable over Lohning et al. (US20020034733) in view of Kozak (Microbiological Reviews, 47(1) 1-45 (1983)).

MPEP §2143 states that for a *prima facie* case of obviousness to be met, three criteria are required: 1) a suggestion or motivation to modify the reference or combine the reference teachings; 2) a reasonable expectation of success; and 3) the combination of the references must suggest all of the claim limitations.

Examiner stated that Lohning et al. fails to disclose a tricistronic vector, but that Kozak discloses that the primary transcript in prokaryotes is polycistronic. The Examiner argues that, therefore, a tricistronic arrangement would be appropriate for such expression in a prokaryotic cell and that the cited references provide a reasonable expectation of success to do so. In addition, Examiner states that one would have been motivated to do so by the desire to obtain simultaneous expression of three genes under the control of a single promoter. Applicant respectfully disagrees.

Kozak fails to provide a suggestion or motivation to modify the dicistronic vectors of Lohning et al. to arrive at the claimed tricistronic vectors. The teachings of Kozak can be considered teachings related to basic biology. In addition, Kozak published in 1983, which is many years before the innovation of Lohning et al., which claims priority back to July 20, 1999. Based upon what the Examiner describes as a high level of skill in the art, the inventors of Lohning et al. would likely have been well aware of the polycistronic nature of

transcription in prokaryotes as described by Kozak. Despite this presumed knowledge, Lohning et al. only describe the use of a dicistronic vector and the utilization of a two vector system (immunoglobulin polypeptides in one vector and Ig-presenting polypeptide in another vector). Kozak provides no motivation to modify the dicistronic vectors of Lohning et al., as Kozak provides no information at all why one would be motivated to develop a tricistronic vector, for example, Kozak describes no problems with the use of dicistronic vectors, proposes no alternatives, nor provides any advantages to using an alternative arrangement.

In addition, the Examiner states that one would have been motivated to develop a tricistronic vector by the desire to obtain simultaneous expression of three genes under the control of a single promoter. Applicant disagrees. Neither reference provides any rationale or any information relevant to a desire to obtain simultaneous expression of three genes under the control of one promoter. Lohning et al. teaches the use of a dicistronic vector and shows that it works for the purposes of a phage display library (see Example 2.1, paras 140-141, Figures 10-13, Example 2.2, paras. 164-165, and Figures 19-22 of US20020034733 Lohning). Based upon the references of record, it was not until the present application, where the inventors describe the challenges in using a dicistronic vector or multi-vector arrangement, such as, the requirement for a selection protocol or need to regulate multiple promoters, and the advantages of using an alternative arrangement.

In conclusion, Kozak provides no suggestion or motivation to modify the dicistronic vectors of Lohning et al. and arrive at the claimed tricistronic vectors, therefore, Applicant respectfully requests the Examiner to withdraw the rejection.

In addition, the Examiner states that the teachings of Kozak in combination with Lohning et al. provide a reasonable expectation of success in the claimed invention. Applicant disagrees. The unpredictability in the art is described in Lohning et al, at Example 2.1, paras. 135-138, results shown in Figures 8-9 and Example 2.2, paras. 160-161, results shown in Figures 17-18, where western blot shows that not all of the polypeptides express at a balanced rate and where some polypeptides later associate in an undesirable manner, as in phage display the VH-CH-pIII is desirable in order to display functional immunoglobulin polypeptides. Kozak adds nothing here, because the basic principle disclosed in Kozak applies to the results in Lohning, where prokaryotic cells used polycistronic transcription, and the results were not predictable. Based upon the cited references, there is no reasonable expectation of success that the claimed tricistronic vectors would work in the phage display context, which based upon the following phrases in the claims, e.g., “display vector”, “prokaryotic promoter” and “phage coat protein” is suggested by the claims. In addition,

there is no reasonable expectation or predictability that the claimed tricistronic vector would be superior to a dicistronic vector, as shown in the results of Table II.

In conclusion, as the combination of Kozak and Lohning et al. provide no reasonable expectation of success in the claimed invention, Applicant respectfully requests the Examiner to withdraw the rejection.

In addition, in order for a *prima facie* case of obviousness to be shown, the combination of the references must suggest all of the claim limitations. Here Kozak fails to suggest the use of a tricistronic vector, therefore, Applicant respectfully requests the Examiner to withdraw the rejection.

## **CONCLUSION**

In view of the foregoing amendments and arguments, Applicants respectfully submit that the application is in condition for allowance. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-4520. **This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. §1.136(a)(3).**

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